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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,549	01/26/2000	DAVID CHARLES BAULCOMBE		8682

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EXAMINER	
PARAS JR, PETER	
ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/491,549	Applicant(s) BAULCOMBE ET AL.	
	Examiner Peter Paras	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-17,21,26-29 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-17,21,26-29 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed on September 24, 2001 has been entered. Claims 1, 5-17, 21, 26-29, and 32-34 are pending and are under current consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 10/27/99. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 1, 5-11, 21, and 32-34 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The previous rejection of claims 1, 5-10, 12-17, 21, 26-29, and 32-34 under 35 U.S.C. 102(a) as being anticipated by Hamilton et al is withdrawn because Hamilton et al was published by the instant inventors. For clarification, the requirement under 35 U.S.C. 102(a) is that the invention was known or used by **others** less than a year before filing of a patent application. However, as priority has not yet been perfected in the instant application and had the Hamilton reference been published by others, the rejection would have been maintained until priority was perfected.

Claims 1, 5-10, 12-17, 21, 26-29, and 32-34 as amended or originally filed are rejected under 35 U.S.C. 102(a) as being clearly anticipated by a meeting presentation at Leysin, Switzerland, February 25-28, 1999 (IDS C6). The previous rejection is maintained for the reasons of record advanced in the Office action mailed on 6/21/01 on page 4.

Applicant's arguments filed on September 24, 2001 have been fully considered but they are not persuasive. Applicants have argued that the overhead projections of the meeting presentation were presented by one of the Applicants in Switzerland less than a year before Applicant's earliest effective priority date. See page 5 of the request for reconsideration.

In response, the Examiner asserts that the meeting presentation was made by **one** of the inventors (as indicated by Applicants) which constitutes a different inventive entity. A different inventive entity meets the requirement under 35 U.S.C. 102(a) as the meeting presentation was made within a year of Applicant's filing date. In this case

perfection of priority would not overcome the instant rejection because the meeting date does not fall between the U.S. filing date and the filing date of the British priority document. Accordingly, the rejection is maintained for the reasons of record and as discussed in the preceding paragraph.

The previous rejection of claims 1, 5-10, 12-17, 21, 26-29, and 32-34 under 35 U.S.C. 102(a) as being clearly anticipated by Hamilton et al (poster presentation, 1999, IDS-C7) is withdrawn as the poster presentation was by the instant inventive entity and the requirement under 35 U.S.C. 102(a) is that the invention was known by **others**. See the recitation of 35 U.S.C. 102(a) above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-17, 21, 26-29, and 32-34 as amended or originally filed are rejected under 35 U.S.C. 103(a) as being unpatentable over Waterhouse et al and Wassenegger et al taken with Dougherty et al. The previous rejection is maintained for the reasons of record advanced in the Office action mailed on 6/21/01 on pages 5-10.

Applicant's arguments filed on September 24, 2001 have been fully considered but they are not persuasive. Applicants have argued that there would not have been a

reasonable expectation of success by combining the teachings of the cited references to arrive at the claimed invention. Applicants assert that only with the benefit of hindsight reasoning could the instant invention be obvious. See the request for reconsideration on pages 5-7.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As indicated in the Office action mailed on 6/21/01, Waterhouse has taught post-transcriptional gene silencing (PTGS) in transgenic tobacco plants (see page 6) and both Wassenegger and Doughtery have suggested that small RNA molecules, ranging from 10-100bp may be responsible for gene silencing (see pages 6 and 7 respectively). As it was known in the art that small RNA molecules (10-100bp) may be responsible for gene silencing as evidenced by Wassenegger and Doughtery, the references have provided ample motivation (to elucidate the mechanism of PTGS as suggested by both Wassenegger and Doughtery, see page 8 of the Office action of 6/21/01) for identifying such RNA molecules in plants. See pages 8-9 of the Office action mailed on 6/21/01. The Examiner has not relied on hindsight reasoning to combine the cited references to arrive at the claimed invention because the references

have clearly suggested that small RNA molecules may responsible for gene silencing and that there was an art-recognized need to identify such RNA molecules to elucidate the mechanism of PTGS as suggested by both Wassenegger and Doughtery.

In response to applicant's argument that there was not a reasonable expectation for success to arrive at the claimed invention by combining the teachings of Waterhouse, Wassenegger, and Doughtery, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The combination of references (Waterhouse, Wassenegger, and Doughtery) has taught that gene silencing may occur by formation of double-stranded RNA molecules between a target RNA molecule and a small RNA molecule, such as the SRMs required by the instant claims, as well as the use of Northern blotting to identify such molecules and that the RNA molecules that may be responsible for gene silencing may range in size from 10-40 base, particularly between 10-21 bases in length. See pages 5-10 of the Office action of 6/21/01. The combination of references has provided ample motivation for identifying small RNA molecules that may be involved in PTGS.

Accordingly, the rejection is maintained for the reasons of record and as discussed in the preceding paragraphs.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

Art Unit 1632

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